UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

JOSHUA DAVID FRISKE, INDIVIDUALLY AND AS PERSONAL REPRESENTATIVE OF THE ESTATE OF KATHRYN FRISKE; JEREMY FRISKE, INDIVIDUALLY AND AS PERSONAL REPRESENTATIVE OF THE ESTATE OF KATHRYN FRISKE; BILLY RAY STAPP; AND GLORIA STAPP, Plaintiffs, vs. ALZA CORPORATION AND SANDOZ INC., Defendants.	CIVIL ACTION NO. 3:11–CV–130–F

DEFENDANTS' MOTION FOR PARTIAL DISMISSAL, AND BRIEF IN SUPPORT

Pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, Defendants ALZA Corporation and Sandoz Inc. ("Defendants") hereby respectfully move this Court for a partial dismissal of Plaintiffs' Complaint. Specifically, Defendants seek dismissal of the marketing defect, design defect, negligent misrepresentation, and breach of implied warranty of fitness claims asserted by Plaintiffs Joshua David Friske, individually and as personal representative of the estate of Kathryn Friske, Jeremy Friske, individually and as personal representative of the estate of Kathryn Friske, Billy Ray Stapp, and Gloria Stapp (collectively, "Plaintiffs") in their Complaint. *See* Complaint [Dkt. No. 1], §§ IV.C. (p. 12, ¶¶ 13–17), IV.D. (p. 13, ¶¶ 18–22), IV.E. (p. 13-14; ¶¶ 23-26), IV.F. (pp. 16–18, ¶¶ 27–30), and IV.G. (p. 18, ¶¶ 31–34).

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Plaintiffs have sued Defendants for the alleged wrongful death of Kathryn Friske. Plaintiffs allege that at the time of her death, Ms. Friske was using a prescription pain patch (the "Patch") designed, manufactured, and marketed by Defendants. Complaint [Dkt. No. 1], § III (p. 5, ¶ 7). The Patch contains the narcotic fentanyl, which is absorbed transdermally (through the skin) once applied. *Id.*, § III (p. 6, ¶¶ 9, 10). Plaintiffs bring claims for strict liability based on alleged manufacturing, marketing, and design defects related to the Patch; negligence; negligent misrepresentation; breach of implied warranty of fitness; and gross negligence. *Id.*, § IV.A–H (pp. 9–19, ¶¶ 4–37).

Plaintiffs' marketing defect claim is based on allegations that Defendants "failed to warn of risks and dangers" allegedly associated with use of the Patch, and that "[t]he absence of such warnings and/or instructions made the product unreasonably dangerous at the time of sale. . . ." *Id.*, § IV.C. (p. 12, ¶¶ 13, 15). Plaintiffs acknowledge in their Complaint, as they must, that "the FDA approved the initial proposed labeling for the Patch," and that "the FDA approved revised labeling proposed by Defendants." *Id.*, § III (p. 8, ¶ 17). Plaintiffs claim, however, that the United States Food and Drug Administration ("FDA") "did not have full knowledge" of product risks, because "Defendants failed to provide the FDA with existing evidence of product defects and the risks associated with [the Patch] as such evidence was obtained, or should have been obtained." *Id.*, § III (p. 8, ¶ 17).

Plaintiffs' marketing defect claim fails because Texas law provides a presumption that pharmaceutical manufacturers are not liable for alleged failures to provide adequate warnings if the warnings were approved by the FDA. TEX. CIV. PRAC. & REM. CODE § 82.007(a)(1). That presumption is only rebuttable in enumerated circumstances not present here. *Id.*, § 82.007(b).

Plaintiffs' allegation that Defendants withheld information from the FDA is insufficient, as a matter of law, to overcome the presumption. *See, e.g., Ledbetter v. Merck & Co.*, Nos. 2005–58543 and 2005–59496, 2007 WL 1181991 (Tex. Dist.—Harris, Apr. 19, 2007) (a courtesy copy of which is attached as Exhibit A). In the alternative, even if the presumption were not applied, Plaintiffs' marketing claim still fails because it is not adequately pleaded under *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007) and *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009).

Plaintiffs' negligent misrepresentation claim is also based on failure-to-warn allegations. Plaintiffs assert that "**Defendants failed to communicate to the FDA**, Decedent, physicians, distributors, pharmacists, and/or the general public, that proper use of the Patch could cause serious injury and/or death." Complaint [Dkt. No. 1], § IV.F. (p. 16, ¶ 27) (emphasis added). Plaintiffs' conclusory negligent-misrepresentation allegations, including those based on withholding information from the FDA, fail for the same reasons their marketing defect claim fails.

With respect to their design defect claim, Plaintiffs allege that the Patch was unreasonably dangerous because Defendants utilized a "reservoir" design to manufacture the Patch, instead of a "'matrix" design or "sealed multi-laminate" design, which Plaintiffs claim were safer alternative designs. *Id*., § IV.D. (p. 13, ¶ 19). Under Texas law and comment k to section 402A of the RESTATEMENT (SECOND) OF TORTS, however, Defendants cannot be held liable for claims based on design defects in prescription drugs.

As for their claim for breach of implied warranty of fitness, Plaintiffs allege that the Patch "was unfit for the particular purposes for which it was purchased." *Id*., § IV.G. (p. 18, ¶¶ 32–33). This claim fails because Plaintiffs have not alleged the essential elements of such claim, including that the product was used for a particular, non-ordinary purpose.

II. ARGUMENTS AND AUTHORITIES

A. Plaintiffs' marketing defect claim fails.

Plaintiffs' claim against Defendants based on a marketing, or warning, defect fails as a matter of law for two reasons: (1) Texas law creates a presumption — which Plaintiffs cannot rebut — that FDA-approved warnings are adequate; and (2) Plaintiffs have not alleged, and cannot allege, facts sufficient to state a marketing defect claim.

1. The Patch's FDA-approved warnings are presumed adequate under Texas law.

Texas law presumes FDA-approved warnings to be adequate. TEX. CIV. PRAC. & REM. CODE § 82.007(a)(1). Thus, pharmaceutical defendants are generally not liable for defective warnings if the FDA approved those warnings. Section 82.007 of the Texas Civil Practice & Remedies Code provides that "there is a rebuttable presumption that the defendant or defendants . . . are not liable with respect to the allegations involving failure to provide adequate warnings or information if: (1) the warnings or information that accompanied the product in its distribution were those approved by the United States Food and Drug Administration . . . ." *Id.*; *see also Ebel v. Eli Lilly & Co.*, 536 F. Supp. 2d 767, 773–74 (S.D. Tex. 2008) ("Under Texas law, [ ] FDA approval creates a rebuttable presumption that the approved warning is adequate."); *Holland v. Hoffman-La Roche, Inc.*, No. 3:06–CV–1298–BC, 2007 WL 4042757, *2–3 (N.D. Tex., Nov. 15, 2007) (Kaplan, J.) ("Here, plaintiff presents no evidence to rebut the presumption that the FDA-approved warnings and information . . . were adequate. . . . . Defendant is therefore entitled to summary judgment with respect to plaintiff's failure-to-warn claim.").

Here, there is no dispute that the FDA approved the warnings that accompanied the Patch. Complaint [Dkt. No. 1], § III (p. 8, ¶ 17). Thus, Defendants are entitled to the presumption that the warnings for the Patch were adequate.

2. Federal law preempts Plaintiffs' only alleged exception to the presumption against liability for FDA-approved warnings: fraud-on-the-FDA under Section 82.007(b)(1).

Plaintiffs cannot overcome the presumption against liability for FDA-approved warnings in Section 82.007 by pointing to their claim Defendants withheld information from the FDA. That argument fails because such an exception to the presumption, set forth in Section 82.007(b)(1),[1] is preempted under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001) — at least where, as here, there is no indication that the FDA *itself* determined that information was withheld. While there is a split in authority as to the applicability of *Buckman* to statutory presumptions, the better-reasoned cases hold that *Buckman* applies in these circumstances. The cases that do not adhere to *Buckman* — none of which is binding on this Court — base their decisions on a meaningless distinction between a direct, stand-alone claim for fraud-on-the-FDA (as in *Buckman*) and a claim for fraud-on-the-FDA used to rebut a presumption of non-liability (as here). Well-reasoned cases explain how this is a distinction without a difference. The concerns of *Buckman* (that the FDA is responsible for policing fraud and drug manufacturers may deluge the FDA with unwanted information to avoid liability for claims that they withheld information) are equally present whether the plaintiff seeks to establish liability through a stand-alone fraud-on-the-FDA claim or by defeating a statutory presumption of non-liability with a claim of fraud-on-the-FDA.

a) Several courts have held that the fraud-on-the-FDA exception in Section 82.007(b)(1) is preempted under *Buckman*.

A claimant may overcome the presumption against liability for FDA-approved warnings only by establishing the applicability of a statutory exception. TEX. CIV. PRAC. & REM. CODE

[1] The other exceptions in Section 82.007(b)(2)-(5) relate to sales of recalled products, off-label use, and bribery, which Plaintiffs have not alleged. *See* TEX. CIV. PRAC. & REM. CODE 82.007(b).

§ 82.007(b); *In re Aredia & Zometa Products Liability Litigation*, Nos. 3:06–MD–1760 *et al.*, 2008 WL 2944910 (M.D. Tenn. July 25, 2008), *5 ("Subsection (b) limits the ways in which a plaintiff can rebut the presumption of subsection (a)"). Section 82.007(b)(1) states that a claimant may rebut the non-liability presumption if a defendant "withheld from or misrepresented to the [FDA] required information that was material and relevant to the performance of the product and was causally related to the claimant's injury." *Id.*, § 82.007(b)(1). Although Plaintiffs allege that Defendants withheld information from the FDA, those allegations do not save their marketing defect claim because Section 82.007(b)(1) has been held invalid except in limited circumstances not present here.

In *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), the United States Supreme Court held that federal law — specifically, the Medical Devices Act — preempts state-law claims of fraud on the FDA. The Court observed that "policing fraud against federal agencies is hardly 'a field which the States have traditionally occupied'"; rather, "the relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." *Id.* at 347 (citing *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947); *Boyle v. United Techs. Corp.*, 487 U.S. 500, 504–05 (1988)). Noting disclosure requirements and provisions aimed at "detecting, deterring, and punishing" false statements made during FDA processes of approving medical devices, the Court held that state law fraud-on-the-FDA claims "inevitably conflict" with, and are thus preempted by, the FDA's task of policing fraud. *Id.* at 349–50. The Court explained that the "conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the administration, and that this authority is used by the administration to achieve a somewhat delicate balance of statutory objectives." *Id.* at

348–49. The Court articulated the concern that applicants might submit "a deluge of information that the Administration neither wants nor needs" for fear that disclosures to the FDA would be judged insufficient under a state law. *Id.* at 350–51, 353.

Several courts have held that the "fraud-on-the-FDA" exception in Section 82.007(b)(1) is preempted under *Buckman*. In *Ledbetter v. Merck & Co.*, Nos. 2005–58543 and 2005–59496, 2007 WL 1181991 (Tex. Dist.—Harris, Apr. 19, 2007), the Texas MDL court presiding over the Vioxx litigation reached that same conclusion. The court rejected the plaintiffs' argument that *Buckman* was distinguishable because it involved a medical device rather than a drug, stating, "The same analysis must apply with no less force to drug manufacturers. Indeed, the State of Texas, by enacting the Texas Act, has placed the relationship between drug manufacturer and FDA in issue." *Id.* at *5. The court also rejected the plaintiffs' argument that *Buckman* was inapplicable because it involved a suit based entirely on a fraud-on-the-FDA theory, as opposed to traditional state-law-based products liability, holding:

> Whether it is an element of plaintiffs' cause of action, or a way to defeat an affirmative defense, the proof is the same. All of the federalism concerns expressed in *Buckman* still apply. The requisite showing under the Texas Act is analogous to and sufficiently equivalent to plaintiffs' asserting a claim of fraud on the FDA that the claim is preempted under *Buckman.*

Id. The court further reasoned: "Given the extent of federal regulation, and the extent to which the FDA is empowered to investigate and regulate drug manufacturers who fail to provide required information, permitting a Texas jury or judge to make the same inquiry would impinge on a uniquely federal issue." *Id.* at *6. The court concluded:

> All of the concerns raised by the Supreme Court in *Buckman* would manifest themselves if the motion for summary judgment were denied. *Buckman* noted that manufacturers might 'deluge' the FDA with information it neither needed nor wanted in order to defend state tort claims. 531 U.S. at 351. This could potentially impede the regulatory process. The *Buckman* concern of deluging the FDA could well come true if manufacturers were forced to make data

> submissions defensively in order to ensure that the presumption of the Texas Act remained in place.

Id. at 6.

Although the *Ledbetter* court noted that plaintiffs could rebut the presumption against liability for FDA-approved warnings if the FDA *itself* determined that a drug manufacturer withheld information from or misrepresented information to the FDA, that circumstance is not alleged here. *Id.* ("such 'inter-branch-meddling concerns that animated *Buckman*' do not arise when the 'FDA *itself* determines that a fraud has been committed on the agency during the regulatory-approval process.'") (quoting *Garcia v. Wyeth-Ayerst Laboratories*, 385 F.3d 961, 966 (6th Cir. 2004) (emphasis in original)).

Similarly, the Middle District of Tennessee, applying Texas law, held that the exception under Section 82.007(b)(1) was preempted, reasoning that:

> In order to pursue their failure-to-warn claims, Plaintiffs are required to prove that material and relevant information was withheld from the FDA. Whether that evidence is characterized as an element of Plaintiffs' proof or a 'defense' to the presumption of this statute, the proof is the same. The federalism concerns of *Buckman* and *Garcia* are still present. The Court finds that requisite showing under the Texas statute is analogous to and sufficiently equivalent to asserting a claim of fraud on the FDA that the claim is preempted under *Buckman*.

In re Aredia & Zometa Products Liability Litigation, Nos. 3:06–MD–1760 *et al.*, 2008 WL 2944910 (M.D. Tenn. July 25, 2008), *4-5.

Last year, Judge Lindsay of the United States District Court for the Northern District of Texas, Dallas Division, granted summary judgment on marketing defect and negligence claims in a pharmaceutical case for the same reasons *Buckman* held a fraud-on-the-FDA claim preempted. *Lofton v. McNeil Consumer & Specialty Pharms.*, 682 F. Supp. 2d 662 (N.D. Tex. 2010). The court found "that the concerns in *Buckman* hold true not only where a plaintiff brings a fraud-on-the-FDA claim but also where it seeks to show an exception to the [Section 82.007]

presumption . . . ." *Id.* at 675. Judge Lindsay further recognized that "[t]o avoid any intrusion upon the FDA's right to police fraud itself," preemption is required where a plaintiff "ask[s] the court to reach the conclusion opposite of that reached by the FDA." *Id.*[2]

Plaintiffs may argue that the Fifth Circuit's decision in *Hughes v. Boston Scientific Corp.*, — F.3d —, 2011 WL 184554 (5th Cir. Jan. 21, 2011) supports their warning defect claim, but that case is inapplicable because the evidence there suggested that the FDA *itself* concluded that the defendant failed to satisfy its reporting requirements. In *Hughes*, the court held that *Buckman* did not require preemption of a negligence per se claim under Mississippi law. *Id.* at *12. The plaintiff in *Hughes* asserted that the defendant failed to follow the FDA's Medical Device Reporting ("MDR") regulations with respect to reporting burns associated with the use of the product at issue. But the court was not confronted with the concern, addressed in *Buckman*, that manufacturers might submit "a deluge of information that the Administration neither wants nor needs." *Buckman*, 531 U.S. at 353. To the contrary, there was evidence in *Hughes* that the FDA itself disapproved of the defendant's practices with respect to reporting some types of burns but not others, and actually "directed" the defendant to report all burns caused by the product at issue. *Hughes*, 2011 WL 184554, at *10. The court noted that the "evidence strongly suggests that the FDA concluded that Boston Scientific's algorithm failed to satisfy the MDR regulations requiring reports of 'serious injuries.'" *Id.*; *see also Ledbetter*, 2007 WL 1181991 ("'concerns that animated *Buckman*' do not arise when the 'FDA *itself* determines that a fraud has been

[2] In ruling on a motion for reconsideration, Judge Lindsay narrowed the holding to the facts of the case, in which the FDA itself had made a determination that it had "no evidence that there is additional undisclosed safety information that was withheld by ibuprofen manufacturers." *Lofton v. McNeil Consumer & Specialty Pharmaceuticals*, Civil Action No. 3:05-CV-1531-L, 2010 WL 2484505, *3 (N.D. Tex., June 17, 2010). Judge Lindsay determined that the holding "does not implicate the FDA's right to determine whether parties have committed fraud upon it," but did not decide whether or not Section 82.007(b)(1) would have been preempted outside the narrow circumstances of that case (i.e. if the FDA had not made a determination touching on the issue of fraud). *Id.*

committed on the agency during the regulatory-approval process.'") (quoting *Garcia,* 385 F.3d at 966 (emphasis in original)). In contrast, there is no allegation in the present case that the FDA made any determination with respect to Defendants' reporting procedures. Thus, while the *Buckman* rationale was inapplicable in *Hughes,* it applies with full force in the present case.

This Court should follow the cases cited above which hold that the fraud-on-the-FDA exception in Section 82.007(b)(1) is preempted under *Buckman*.

b) Cases that do not follow *Buckman* rely on a meaningless distinction between stand-alone claims and claims used to rebut a presumption of non-liability, even though the effect on defendants and the FDA is the same.

The District of New Jersey reached the opposite conclusion in *Yocham v. Novartis Pharmaceuticals Corp.*, Civil Action No. 07-1810, 2010 WL 3502670 (D.N.J. Aug. 31, 2010). The court based its holding on the argument that a stand-alone tort for fraud on the FDA substantially incentivizes drug manufacturers to deluge the FDA with information, while the availability of a presumption against liability would not. *Id.* at *14. The court offered no support for that conclusion. As the *Ledbetter* and *Aredia* courts indicate, the incentive to avoid liability by deluging the FDA with information is the same whether the threat is from an affirmative cause of action or the avoidance of a presumption against liability.

In an unpublished 2007 decision, Judge Means of the United States District Court for the Northern District of Texas, Fort Worth Division, denied a motion for summary judgment where the defendant raised the issue of preemption in the context of Section 82.007. *Pustejovsky v. Wyeth,* Civil Action No. 4:07-CV-103-Y (N.D. Tex., Nov. 29, 2007). Although the court acknowledged the *Buckman* Court's holding that "state law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud. . . .," the court noted that "section 82.007 does not create a cause of action for fraud on the FDA. . . ; it merely creates a presumption that

[the defendant] may rely upon in its defense." *Id.* at *3 (citing *Ackermann v. Wyeth Pharms.*, 471 F. Supp. 2d 739, 749-50 (E.D. Tex. 2006)). Judge Means did not articulate any further reasoning for his decision.

c) Cases within other circuits are also split, with the better-reasoned cases holding fraud-on-the-FDA claims are preempted when used to rebut statutory presumptions of non-liability.

In *Garcia v. Wyeth-Ayerst Labs.*, 385 F.3d 961 (6th Cir. 2004), the Sixth Circuit held that federal law preempted a fraud-on-the-FDA exception to a statutory presumption of non-liability under Michigan law, similar to the Texas statute at issue here. The court held that a plaintiff may proceed under the "fraud-on-the-FDA" exception to Michigan's analogous FDA immunity statute only where the "the FDA itself determines that a fraud has been committed on the agency during the regulatory-approval process." *Id.* at 965–66 (emphasis removed). Other courts have reached similar results. S*ee, e.g.*, *Grange v. Mylan Labs.*, Civil Action No. 1:07–CV–107–TC, 2008 WL 4813311, at *7 (D. Utah Oct. 31, 2008) (finding that Utah's "fraud-on-the FDA" exception is preempted because otherwise "state courts [would be] essentially second-guessing the FDA and drug companies, nervous about state litigation, [would] have an incentive to flood the FDA with information"); *Henderson v. Merck & Co.*, Civil Action No. 04–CV–05987–LDD, 2005 WL 2600220, at *11 (E.D. Pa. Oct. 11, 2005) (holding that the "fraud-on-the-FDA" exception in Michigan's FDA immunity statute is preempted absent an FDA finding of fraud); *Kobar v. Novartis Corp.*, 378 F. Supp. 2d 1166, 1172–74 (D. Ariz. 2005) (concluding that language in Arizona's punitive damage statute similar to Texas's "fraud-on-the-FDA" exception is preempted by federal law); *Miller v. ALZA Corp.*, — F.Supp.2d —, 2010 WL 5287514, at *13 (S.D. Ohio, Dec. 17, 2010) (stating: "Claims asserting fraud on the FDA are preempted by the Food, Drug and Cosmetics Act" and holding that plaintiffs' claims "premised on alleged

fraudulent withholding of information or making representations to the FDA, are preempted. . .") (citing *Garcia*, 385 F.3d at 965; *Buckman*, 531 U.S. at 350; *In re Aredia and Zometa Products Liab. Litig.*, 352 Fed. Appx. 994 (6th Cir. 2009)).

While the Second Circuit reached a different conclusion in *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2d Cir. 2006), several courts have declined to follow that case and have followed the Sixth Circuit's holding in *Garcia* instead. *See Lofton v. McNeil Consumer & Specialty Pharmaceuticals*, No. 3:05-CV-1531-L, 2010 WL 2484505 (N.D. Tex., June 17, 2010), *3 (finding, after reconsideration, that the court's "reliance on *Garcia* and similar cases and rejection of *Desiano* also should not be altered."); *White v. SmithKline Beecham Corp.*, 538 F. Supp. 2d 1023, 1029 (W.D. Mich. 2008) (declining to follow *Desiano*, instead following *Garcia*, and granting the defendant's motion for judgment on the pleadings in the absence of any allegation that the FDA itself determined it had been bribed or defrauded).[3]

The United States District Court for the Southern District of Florida in the *Trasylol Products Liability Litigation* explained why the holding and reasoning of *Garcia*, rather than *Desiano*, is correct. *In re Trasylol Products Liability Litigation*, — F. Supp. 2d —, Civil Action No. 1:08-MD-01928, 2010 WL 5579867 (S.D. Fla. May 10, 2010). Confronted with this split in authority, the *Trasylol* court found that "the rationale of the Sixth Circuit's decision in *Garcia* to be more persuasive." *Id.* at *9. The court reasoned:

> The concerns expressed by the Supreme Court in *Buckman* hold true not only where there is a separate fraud-on-the-FDA claim but also where a plaintiff seeks

[3] Although the United States Supreme Court affirmed *Desiano*, the Justices split on a 4-4 vote, Justice Roberts having recused himself. *Warner-Lambert Co., LLC v. Kent*, 552 U.S. 440 (2008). The affirmance is thus without precedential value. *See, e.g., U.S. v. Pink*, 315 U.S. 203, 216 (1942) ("The lack of an agreement by a majority of the Court on the principles of law involved prevents it from being an authoritative determination for other cases."); *In re Trasylol Products Liability Litigation*, Civil Action No. 1:08-MD-01928, — F. Supp. 2d —, 2010 WL 5579867, at n.13 (S.D. Fla. May 10, 2010) ("Judgment entered by an equally divided Court is not entitled to precedential weight.") (quoting *Trans World Airlines, Inc. v. Hardison*, 432 U.S. 63, 73 n. 8 (1977)).

> to prove fraud on the FDA in order to bring a traditional state-law torts suit. If the Court were to find fraud-on-the-FDA when the FDA itself has not made such a finding, the Court would be intruding upon the FDA's right to police itself and second-guessing what the FDA would have done had it received the information that was allegedly withheld from it by the defendant-company.

Id. The court therefore granted the defendant's motion *in limine* and excluded evidence, testimony, and argument that the defendant provided inadequate or incomplete data to the FDA. *Id.* at 14.

d) The Supreme Court's holding in *Wyeth v. Levine* is inapplicable to this case.

Plaintiffs may attempt to rely on *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), in which the Supreme Court held that federal law (*i.e.*, FDA-approval) does not preempt a state-law failure to warn claim against a drug manufacturer. *Wyeth* held that the Food, Drug, and Cosmetic Act ("FDCA") did not preempt a state common-law failure to warn claim. In contrast, this case deals with a Texas statutory presumption that FDA-approved warnings are adequate. *Wyeth's* holding is inapplicable to state statutory presumptions such as that at issue in this case. In rejecting the plaintiff's argument that *Wyeth* limited the holding of *Buckman*, the *Trasylol* court explained how the two cases address different issues: "*Buckman* and *Wyeth* can be reconciled: while traditional state-law claims for failure to warn are not impliedly preempted by the FDCA, fraud-on-the-FDA claims are impliedly preempted by the FDCA." *In re Trasylol Products Liability Litigation*, 2010 WL 5579867, at *9. Here, Defendants are not arguing that plaintiffs' state-law warning defect claims are preempted by federal law (which would be inconsistent with *Wyeth*); rather, those claims are presumptively barred under *Texas* law through Section 82.007. Plaintiffs' fraud-on-the-FDA allegations are preempted under *Buckman* and cannot be used to overcome the statutory presumption against liability.

e) The Court should adopt the holding of the better-reasoned cases and find the exception under Section 82.007(b)(1) preempted in this case.

The cases cited above that have examined the issue in detail set forth good reasons for holding the fraud-on-the-FDA exception in Section 82.007(b)(1) preempted under *Buckman* — stand-alone claims for fraud on the FDA have the same effect as fraud-on-the-FDA claims used to rebut a presumption of non-liability. Whether to avoid liability for a stand-alone claim or to defeat a claim used to rebut a presumption of non-liability, the prospect of liability will encourage drug manufacturers to submit additional, potentially unwanted, data to the FDA contrary to the Supreme Court's direction in *Buckman*.

Defendants urge the Court to adopt the rule articulated by Judge Lindsay and other courts that claims of fraud on the FDA, when asserted to rebut the presumption against liability for FDA-approved warnings, are preempted.

3. Plaintiffs have not adequately pleaded any exception to Section 82.007.

Even if their claims of fraud on the FDA were not preempted, Plaintiffs' marketing defect claim would fail because they have not alleged, and cannot allege, facts sufficient to overcome the presumption of non-liability based on a marketing defect.

A complaint must contain "enough facts to state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 570; *see also Iqbal*, 129 S. Ct. at 1949. Conclusory allegations or legal conclusions will not suffice. *Twombly*, 550 U.S. at 555. Instead, the complaint's "factual allegations must be enough to raise a right to relief above the speculative level on the assumption that all the allegations in the complaint are true." *Id.*

Here, Plaintiffs have not alleged any facts supporting their right to relief on the basis that Defendants withheld information from, or made misrepresentations to, the FDA, as required under section 82.007(b)(1). Instead, Plaintiffs vaguely allege in the Complaint that "Defendants failed to provide the FDA with existing evidence of product defects and the risks associated with [the Patch] as such evidence was obtained. . . ." Complaint [Dkt. No. 1], § III (p. 8, ¶ 17) (emphasis added). This allegation is both conclusory and speculative. Plaintiffs have not alleged what information Defendants should have conveyed to the FDA, and they merely speculate that some unspecified evidence was obtained but not provided to the FDA.

Further, the heightened pleading standard set forth in Rule 9(b) of the Federal Rules of Civil Procedure applies to Plaintiffs' failure-to-warn claim because that claim hinges on allegations of fraud or mistake. As discussed in Section II.A.2. above, Plaintiffs seek to invoke the fraud-on-the-FDA exception to Section 82.007 by establishing that Defendants "withheld from or misrepresented to the [FDA] required information that was material and relevant to the performance of the product and was causally related to the claimant's injury." *See* TEX. CIV. PRAC. & REM. CODE 82.007(b)(1). In other words, Plaintiffs seek to establish that Defendants — either by fraud or mistake — withheld information or made material representations to the FDA. Rule 9(b) requires a party alleging fraud or mistake to "state with particularity the circumstances constituting fraud or mistake." FED. R. CIV. P. 9(b).

At a minimum, Plaintiffs must provide "allegations of the particulars of time, place, and contents of the false representations, as well as the identity of the person making the misrepresentation and what he obtained thereby." *Shushany v. Allwaste, Inc.*, 992 F.2d 517, 521 (5th Cir. 1993). Plaintiffs must allege the "who, what, when, where, and how" of the alleged fraud. *United States ex. rel. Willard v. Humana Health Plan of Texas Inc.*, 336 F.3d 375, 384

(5th Cir. 2003) (citing *United States ex. rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 903 (5th Cir. 1997)). The purposes of Rule 9(b) are: "to ensure that the plaintiff has investigated and reasonably believes a fraud has occurred;" "to provide adequate notice to defendants so that they can respond to the plaintiff's claims;" "to protect the reputation of defendants;" and "to preclude litigants from filing baseless complaints and then attempting to discover unknown wrongs." *Tuchman v. DSC Commc'ns Corp.*, 818 F. Supp. 971, 977 (N.D. Tex. 1993).

Plaintiffs' Complaint does not meet this heightened pleading requirement. Plaintiffs do not allege facts showing the "who, what, when, where, and how" of any alleged fraud or misrepresentations. Instead, they vaguely allege that "Defendants failed to provide the FDA with existing evidence of product defects and the risks associated with [the Patch] as such evidence was obtained. . . ." Complaint [Dkt. No. 1], § III (p. 8, ¶ 17).

From the face of Plaintiffs' complaint, it is apparent that Section 82.007(a)'s presumption applies to bar liability based on a marketing defect, and Plaintiffs have not pleaded facts to show any plausible way they can overcome that presumption. Thus, Plaintiffs' claim for marketing defect fails as a matter of law and should be dismissed.

B. Plaintiffs' negligent misrepresentation claim fails for the same reasons.

Likewise, Plaintiffs' claim for negligent misrepresentation fails. Plaintiffs allege that Defendants "failed to communicate to the FDA, Decedent, physicians, distributors, pharmacists, and/or the general public, that proper use of the Patch could cause serious injury and/or death. Defendants instead represented to all such persons/entities that the Patches were safe for use." Complaint [Dkt. No. 1], § IV.F. (p. 16, ¶ 27).

The Court is not bound to accept "labels and conclusions" or "a formulaic recitations of the elements of a cause of action." *Twombly*, 550 U.S. at 555 (citing *Papasan v. Allain*, 478 U.S. 265, 286 (1986)). The complaint must contain sufficient factual matter to state a claim that is plausible on its face, so the court can draw a reasonable inference from the pleadings that a defendant is liable for the misconduct alleged. *Id.* at 570, 556. Here, Plaintiffs do not sufficiently identify any misrepresentations to meet the *Twombly* and Rule 9(b) pleading standards.

Moreover, Plaintiffs' negligent misrepresentation claim is a nothing more than a failure-to-warn claim. The crux of the claim is that the Patch's FDA-approved warnings were inadequate. For the reasons outlined in Section II.A. above, such a claim is preempted and should be dismissed.

C. Plaintiffs' design defect claim fails because Texas law precludes claims based on design defects in prescription drugs.

In Texas, claims involving prescription drugs are governed by comment k to section 402A of the RESTATEMENT (SECOND) OF TORTS. *See, e.g., Reyes v. Wyeth Labs.*, 489 F.2d 1264, 1273 (5th Cir. 1974) (applying Texas law); *Crocker v. Winthrop Labs.*, 514 S.W.2d 429, 433 (Tex. 1974); *Fibreboard Corp. v. Pool*, 813 S.W.2d 658, 688 (Tex. App.—Texarkana 1991, writ denied); *USX Corp. v. Salinas*, 818 S.W.2d 473, 484 (Tex. App.—San Antonio 1991, writ denied). Comment k pertains to "unavoidably unsafe products," which are "incapable of being made safe for their intended and ordinary use," but have benefits that outweigh the hazards of their use. RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965). A prescription drug qualifies as an "unavoidably unsafe product" under comment k because it is a "useful and desirable product, attended with a known but apparently reasonable risk." *Id.*

Under comment k, a manufacturer cannot be held liable for an alleged design defect in a prescription drug. In *Hackett v. G.D. Searle & Co.*, 246 F. Supp. 2d 591 (W.D. Tex. 2002), the

court applied Texas law and held that comment k precluded liability for defective design in the manufacture of prescription drugs. *Id.* at 595 ("under Texas law and comment k of the Restatement, Defendants can only be held strictly liable if the drug was not properly prepared or marketed or accompanied by proper warnings") (citing *Reyes v. Wyeth Labs.*, 498 F.2d at 1264, 1274-75 (5th Cir. 1974)). The *Hackett* court explained the reasoning behind this rule:

> To allow plaintiffs to sue for defective design of prescription drugs would provide a disincentive to companies to develop new drugs and would allow juries to second-guess the FDA's approval of the drugs for marketing.

Hackett, 246 F. Supp. 2d at 595; *see also, e.g., Blackmon v. Am. Home Prods. Corp.*, 328 F. Supp. 2d 659, 664 (S.D. Tex. 2004) (applying Texas law and holding if a prescription drug is "free from manufacturing and warning defects[,] the seller will not be held strictly liable for injuries resulting from risks inherent in the product's design"); *Keene Corp. v. Rogers*, 863 S.W.2d 168, 176 (Tex. App.—Texarkana 1993, no writ) ("[T]he manufacture and sale of unavoidably unsafe products is reasonable despite the risk, so long as the manufacturer or seller properly warns consumers."); *McNeil v. Wyeth*, No. 3-02-CV-2072-L, 2005 U.S. Dist. LEXIS 3477, at *19–20 (N.D. Tex. Mar. 4, 2005), *rev'd on other grounds*, 462 F.3d 364 (5th Cir. 2006); *Brown v. Superior Court*, 44 Cal. 3d 1049, 1069 n.12 (Cal. 1988) (finding that, under comment k, prescription drug manufacturers may be liable for manufacturing defects or failure to warn, but not design defects).

In sum, under comment k to section 402A of the RESTATEMENT (SECOND) OF TORTS and Texas law, Plaintiffs cannot recover on their design defect claim.[4]

[4] Texas law also has a statutory presumption against liability for design defects where "the product manufacturer or seller establishes that the product was subject to pre-market licensing or approval by the federal government, or an agency of the federal government, that the manufacturer complied with all of the government's or agency's procedures and requirements with respect to pre-market licensing or approval, and that after full consideration of the product's risks and benefits the product was approved or licensed for sale by the government or agency." TEX. CIV. PRAC. & REM. CODE § 82.008(c). For the

D. Plaintiffs' claim of breach of implied warranty of fitness for a particular purpose fails because they have not pleaded the essential elements.

Plaintiffs allege that the Patch was "unfit for the particular purposes for which it was purchased," and that "Defendants knew and/or had reason to know that the buyer was relying on the skill and judgement [sic] of the Patch Defendants to select or furnish suitable products." Complaint [Dkt. No. 1], § IV.G. (p. 18, ¶¶ 32–33). The facts pleaded by Plaintiffs do not support a recovery for breach of the implied warranty of fitness. First, Plaintiffs have not alleged that the Decedent Ms. Friske used the Patch for a particular purpose outside its ordinary use. Second, Plaintiffs have not alleged that they provided the required notice of breach.

"Texas courts hold that to maintain an action for breach of the implied warranty of fitness for a particular purpose, the plaintiff must allege that the product was to be used for some purpose different than the product's ordinary purpose . . . . In addition, the comment to § 2.315 provides that a particular purpose 'envisages a specific use by the buyer which is peculiar to the nature of his business whereas the ordinary purposes for which goods are used are those envisaged in the concept of merchantability." *Strauss v. Ford Motor Co.*, 439 F. Supp. 2d 680, 686 (N.D. Tex. 2006) (internal citations omitted). Plaintiffs do not allege that the Decedent used the Patch in a way that was different from the Patch's ordinary purpose. Rather, they allege that the Decedent was prescribed and used the patch "to control the pain [she] suffered as a result of her fibromyalgia and osteoarthritis." Complaint [Dkt. No. 1], § III (pp.4–6, ¶¶ 3, 7). This is exactly the ordinary purpose of the patch, as alleged by Plaintiffs: "Users apply the Patch to

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reasons stated in Section II.A., Plaintiffs have not adequately pleaded an exception to the presumption based on allegations that Defendants "withheld or misrepresented to the government or agency information that was material and relevant to the performance of the product and was causally related to the claimant's injury." *See* TEX. CIV. PRAC. & REM. CODE § 82.008(c)(2). Also for the reasons outlined above, any such exception under Section 82.008(c)(2) (*i.e.*, fraud-on-the-FDA) would be preempted.

their skin to relieve pain." *Id.*, § III (p. 6, ¶ 10). Because the Decedent used the Patch for its ordinary purpose, the claim for breach of implied warranty of fitness fails.

Moreover, to recover under the implied warranty of fitness for a particular purpose, a claimant must "notify the seller of breach or be barred from any remedy." TEX. BUS. & COM. CODE § 2.607(c)(1); *Ketter v. ESC Med. Sys.*, 169 S.W.3d 791, 799 (Tex. App.—Dallas 2004, no pet.) (applying the requirements of Texas Business and Commerce Code § 2.607(c)(1) to claims for breach of express warranty and breach of implied warranty of fitness for a particular purpose). Nowhere have Plaintiffs alleged that they gave any such notice. For this additional reason, the claim for breach of implied warranty of fitness fails.

Because Plaintiffs do not allege that the Decedent had a particular purpose for using the Patch, or that they gave the statutorily-required notice, their claim for breach of implied warranty of fitness for a particular purpose should be dismissed.

III. CONCLUSION

For the foregoing reasons, Defendants respectfully request that the Court grant their Rule 12(b)(6) motion for partial dismissal, and dismiss with prejudice Plaintiffs' claims for marketing defect, design defect, negligent misrepresentation, and breach of implied warranty of fitness. *See* Complaint [Dkt. No. 1], §§ IV.C. (p. 12, ¶¶ 13–17), IV.D. (p. 13, ¶¶ 18–22), IV.E. (p. 13-14; ¶¶ 23-26), IV.F. (pp. 16–18, ¶¶ 27–30), and IV.G. (p. 18, ¶¶ 31–34). Defendants further request that the Court grant them such other and further relief, at law or in equity, to which they may be justly entitled under the circumstances.

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CERTIFICATE OF SERVICE

The undersigned certifies that this document was filed electronically on the 25th day of February, 2011, and, in compliance with Local Civil Rule LR 5.1(d), a copy of this document has been served on counsel for Plaintiffs.

David C. Schulte